FDA 510(k) Premarket Notification

K994237 AT HOME DRUG TEST, MODEL 9063

CLEARED

Dec 30, 1999
14 days to decision

K994237 · Product code: **DKZ** · Toxicology
Source: https://www.510kdatabase.net/k994237/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Dec 16, 1999
Decision date	Dec 30, 1999
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Phamatech**
Location	San Diego, CA, US
Contact	CARL A MONGIOVI
510(k) history	47 submissions · 47 cleared · 1996-2004

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k994237/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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